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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/068,935	11/23/98	PASCUAL	D 47714-5004

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EXAMINER	
GAMBEL, P	
ART UNIT	**PAPER NUMBER**
1644	10/09/01

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☑ Responsive to communication(s) filed on 5/17/01

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 55-111 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☐ Claim(s) _____ is/are rejected.
☐ Claim(s) _____ is/are objected to.
☑ Claim(s) 55-111 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☑ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

–SEE OFFICE ACTION ON THE FOLLOWING PAGES–

DETAILED ACTION

1. Applicant's amendment, 5/17/01 (Paper No. 17), has been entered.
Claims 1-54 have been canceled.
Claims 55 - 111 have been added.

2. Applicant's election of an attachment molecules comprising proteins and glycoproteins, endothelial cells, mannose, selectin or integrin, ICAM-1 and Candida in Paper No. 17 is acknowledged.

However, upon a closer inspection of the claims, particularly in view of the active or critical elements of the claimed vaccine; the following is noted.

It is noted that vaccines appear to comprise a single active or critical element, namely the pathogen adhesin molecule.

Therefore, it appears that claims appear to be drawn to pathogens set forth in claims 73-83, irregardless of the adhesion molecule on a host cell or extracellular matrix

For example, Cutler et al. (U.S. Patent No. 5,578,309) teach Candida albicans vaccines (see entire document, including Background of the Invention, Summary of the Invention, Detailed Description of the Invention and Claims. Therefore, it appears that Cutler et al. teach Candida albicans vaccine that anticipate the claimed and elected invention.

Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

Given that this may not be applicant's intent, the following Restriction is set forth for the following reason.

Given the interpretation that the claims read on the active or critical element of the pathogens set forth in claims 73-83, these pathogens and immunogenic fragments thereof, differ in structure and modes of action to such an extent and require non-coextensive searches to such an extent that they are considered separately patentable. For example, the vaccines encompass a broad, diverse and structural distinct spectrum of pathogens.

The examiner apologizes for any inconvenience to applicant in this matter. However, the claims appear to simply read on well known vaccine formulations of a broad spectrum of pathogens at the time the invention was made.

3. Restriction is required under 35 U.S.C. 121 and 372.
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required in response to this Office Action, to elect a single invention to which the claims must be restricted.

I- LXXVII. Claims 55-90, 95-11, drawn to vaccines comprising pathogen adhesin molecules, classified in Class 424, subclass 184.1.

LXXVIII-CXXXXIV. Claims 91-94, drawn to a method of obtaining a vaccine comprising isolating a pathogen, classified in Class 424, subclass 130.1.

4. At least one of the inventions of Groups I- LXXVII (e.g. claim 1) was found to have no special technical feature that defined a contribution over the prior art of Cutler et al. (U.S. Patent No. 5,578,309).
Cutler et al. teach Candida albicans vaccines (see entire document, including Background of the Invention, Summary of the Invention, Detailed Description of the Invention and Claims. Therefore, it appears that Cutler et al. teach Candida albicans vaccine that anticipate the claimed and elected invention.

As indicated above, it is noted that vaccines appear to comprise a single active or critical element, namely the pathogen adhesin molecule.
Therefore, it appears that claims appear to be drawn to pathogens set forth in claims 73-83, irregardless of the adhesion molecule on a host cell or extracellular matrix

It is noted that it was known in the art that all of the pathogens set forth in claims 73-83 have been placed in compositions or formulations that would read on the claimed vaccines.

The claimed functional and structural characteristics of the claimed vaccines would be inherent properties of prior art compositions, including vaccine compositions, comprising the pathogens set forth in claims 73-83.

Therefore, the Inventions of Group I have been previously described.

Since applicant's Inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and lack Unity of Invention.

No Information Disclosure Statement has been filed with the instant application.

5. The following species elections of record are reiterated herein for applicant's convenience, if these read on the active or critical ingredients of the claimed vaccines. Currently, they appear to be a recitation of the counter ligand or receptor of the pathogens set forth in claims 73-83 and, at most, read on immunogenic fragments of said pathogens.

Again, applicant is invited to clarify the critical structural elements of the claimed vaccines, if said critical or active elements comprise elements other than the pathogens themselves.

In addition to electing a Group from above, applicant is required to elect a species as follows.

A. This application contains claims directed to the following distinct species of Groups I/II/III, wherein the attachment molecule is selected from the group consisting of:
(1) proteins, glycoproteins, (2) glycolipids or (3) carbohydrates.

These species do not share the same or corresponding special technical feature because these species are distinct because their structures and modes of action are different which, in turn, address different pathological conditions and therapeutic endpoints.

B). This application contains claims directed to the following distinct species, wherein the targeted host cells for an attachment molecule is selected from the group consisting of:
(1) leukocytes, (2) endothelial cells, (3) epithelial cells, or (4) cells of the nervous system.

These species do not share the same or corresponding special technical feature because these species are distinct because these targeted structures and modes of action are different which, in turn, address different pathological conditions and therapeutic endpoints.

C). In addition to choosing a targeted cell type, this application contains claims directed to the following distinct species, wherein the targeted ligand is selected from the group consisting of:
(1) N-acetylneuraminic acid, (2) sialic acid, (3) N-acetylglucosamine or glucosamine, (4) N-acetylgalactosamine or galactosamine, (5) galactose, (6) mannose, (7) fucose or (8) lactose.

These species do not share the same or corresponding special technical feature because these species are distinct because their structures and modes of action are different which, in turn, address different pathological conditions and therapeutic endpoints.

D) If applicant elects a protein/glycoprotein, this application contains claims directed to the following distinct species, wherein the attachment molecule is selected from the group consisting of:
(1) selectin or integrin, (2) cytokine, (3) chemokine, or (4) GTP-binding protein.

These species do not share the same or corresponding special technical feature because these species are distinct because their structures and modes of action are different which, in turn, address different pathological conditions and therapeutic endpoints.

E) If applicant elects a GTP-binding protein, this application contains claims directed to the following distinct species, wherein the attachment molecule is selected from the group consisting of:
1) Rho, (2) Ras, (3) Rac, (4) Cdc42, (5) Rab, (6) Ran or (7) Arf.

These species do not share the same or corresponding special technical feature because these species are distinct because their structures and modes of action are different which, in turn, address different pathological conditions and therapeutic endpoints.

F) If applicant elects a selectin/integrin then this application contains claims directed to the following distinct species, wherein the attachment molecule is selected from the group consisting of:
(1) E-selectin, (2) P-selectin, (3) L-selectin, (4) VLA-1, (5) VLA-2, (6) VLA-3, (7) VLA-4, (8) VLA-5, (9) VLA-6, (10) Mac-1, (11) LFA-1, (12) gp150.95, (13) CD41a, (14) CD49, (15) CD51, (16) ICAM-1, (17) ICAM-2, (18) ICAM-3, (19) VCAM, (20) NCAM or (21) PECAM

These species do not share the same or corresponding special technical feature because these species are distinct because their structures and modes of action are different which, in turn, address different pathological conditions and therapeutic endpoints.

G) This application contains claims directed to the following distinct species, wherein the attachment molecule is selected from the group consisting of the microbes selected from the group of:
(1) E. coli, (2) Salmonella, (3) Shigella, (4) Pseudomonas, (4) Proteus, (5) Klebsiella, (6) Aerobacter, (7) Heliobacter, (8) Plasmodium, (9) Brucella, (10) Pasteurella, (11) Leishmania, (12) Trypanosoma, (13) Mycobacterium TB, (14) Legionella, (15) Staphylococcus, (16) Streptococcus, (17) Bordetella, (18) Hemophilus, (19), Aspergillus, (20) Cryptococcus, (21) Candida, (22) Histoplasma, (23) Coccidioides, (24) Phycomycetes, (25) Entamoeba, (26) Giardia, (27) Cryptosporidium, (28) Neisseria, (29) Chlamydia, (30) Treponema, (31) Trichomona, (32) Tritrichomonas, (33) Influenza A, (34) Influenza B, (35) Influenza C, (36) Measles, (37) Mumps, (38) Adenovirus, (39) Rhinovirus, (40), Poliovirus, (41) Hepatitis, (42) Hantavirus, (43) Herpesvirus, (44) Rubella, (45) HIV, Coxsackievirus, (46) Corynebacterium, (47) Clostridium, (48) Yersinia, (49) Vibrio, (50) Entamoeba or (51) Hafnia.

These species do not share the same or corresponding special technical feature because these species are distinct because their structures and modes of action are different which, in turn, address different pathological conditions and therapeutic endpoints.

Applicant should elect a species from (A), (B) and (G) as a single group and in addition, select an additional species from (C), (D), (E) or (F) as appropriate.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

PHILLIP GAMBEL

Phillip Gambel, PhD.
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Technology Center 1600
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